

REMARKS

Applicants respectfully request reconsideration of the Examiner's objections and rejections of the claims in view of the foregoing amendments and following arguments.

Claim Rejections – 35 USC §§ 102

The Examiner rejected Claims 1 – 6 and 22 – 26 as allegedly anticipated by Nagel et al. US Patent No. 4,211,237 A (“Nagel”). The Examiner rejected the rest of the claims as being obvious over Nagel and US Patent Application Publication No. 2005/0267376 to Marossero et al., (“Marossero”), Beach et al., US Patent No. 5,088,498 (“Beach”), or Oriol et al., US Patent No. 5,596,993 (“Oriol”). Applicants respectfully traverse these grounds of rejection as applied to the claims as now amended.

Claims 1-6

The Examiner rejected Claim 1 as being anticipated by Nagel, asserting *inter alia* that Nagel determines a number of fetal movements, citing Col. 11, lines 50 – 61 of that reference. Applicants respectfully reiterate their response from the previous Office Action that cardiac contractions are not fetal movements as used in this art and in Applicants' specification. Rather, “fetal movements” means either “fetal body movement” or “fetal breathing”. Nowhere in Applicants' specification, nor anywhere in the cited references, does the term “fetal movement” consist of or comprise the beating of a fetus's heart.

Applicants' claimed invention uses characteristics of the recorded fetal heartbeat waveform to determine whether the fetus's body has moved. As discussed at page 10, lines 19 to 23 of the Specification, and as required by Claim 1, changes in the shape of the fetal ECG

complex are used to detect fetal body movements. As further described in the Specification at page 11, lines 1 to 22, changes in the shape of the QRS complex between the various forms shown in Figures 5A to 5D are indicative of fetal body movements between the various positions represented by types A to D. Fetal movements, or 'events', are detected by transitions in the ECG shape to those shown in Figure 5 or intermediate shapes part way between (Specification, page 11, lines 13 to 19). "Recording the number and frequency of these transitions over a given recording period ... will provide a measure of fetal activity and hence an indication of fetal well-being" (*Id.*, lines 19 to 22). None of the prior art teaches this technique.

Referring specifically to Nagel, this document teaches the use of an average fetal ECG waveform that is built up during an abdominal fetal and maternal ECG recording (see Column 5, line 54 *et seq.*): "A cross-correlation function [is] derived from the abdominal signal $S(t)$ and the sample EKG $M(t)$. $M(t)$ is the group average (average waveform) of the fetal EKG $E_f(t)$ ", or fetal template. The cross correlation is used to detect the fetal ECG.

Combinations of auto-correlation (AC) and cross-correlation (CC) allow an increased signal to noise ratio so that the fetal heart rate / frequency can be determined (Nagel, step 208, column 10, lines 47 to 50 and column 18, lines 1 to 8). Nagel uses ECG waveform shapes for CC processing but they are not used for the detection of fetal movements or fetal presentation.

More particularly, Nagel does not teach or suggest "an event logger determining from the determined differences [in the shapes of a succession of fetal ECG complex waveforms] a number of changes in fetal spatial presentation or position during [a] period of time" as now required by claim 1.

In fact, Nagel does not discuss "fetal movements", as this term is used by Applicants and others skilled in the art, at all. Although Nagel mentions "muscle movements which are a

function of cardiac movements" (Column 11, lines 53 and 54), note that the present invention as claimed relates to fetal movements resulting in a change in fetal presentation or position, e.g. fetal body and limb movements (page 3, line 5). It is clear that cardiac muscle movements are not considered in this category not least because temporary accelerations in heart rate are widely recognized as an indicator of fetal movement (page 2, line 4) and therefore not "fetal movements" *per se*. Also, since conventional Doppler techniques used to assess fetal movements (page 4, line 2 *et seq.*) actually exclude fetal heart rate frequencies (page 5, lines 4 to 10 and page 6, lines 7 to 26) it is clear that the person of ordinary skill in this art does not regard cardiac muscle movements as "fetal movements".

Still further, Nagel teaches away from the present invention in that the proposed technique could not work for such fetal movements. Nagel, Column 11, lines 48 *et seq.* states:

"a rectifier ... is provided in the signal input so as to effect full wave rectification of the input signal without integration in a conventional circuit arrangement. This solution is of advantage during recording of myographic signals i.e. signals derived from muscle movements which are a function of cardiac movements, if the input signal to be detected has no fixed polarity. This results in the advantage, for use in recording the fetomaternal electrocardiogram, that the electrodes need not be placed in every case so that only positive or only negative peaks can be expected ..."

Thus, as the heart pumps it produces myographic signals (i.e. ECG signals) which could either be positive or negative depending on the position of the electrodes. Hence if one rectifies the signal then the resulting signal is always positive. Once a signal is rectified then detection of fetal movements that result in changes in shape towards either positive or negative ECG's will be lost.

In addition to the arguments above, the Applicants have amended Claim 1 to specifically claim that the event logger determines *a number of fetal spatial presentation and/or position*

changes during a given period of time. Nowhere does Nagel teach determining the fetal spatial presentation or positions or determining the number of spatial position changes to determine the health of the fetus. As a result, Applicants respectfully request reconsideration of Examiner's rejection of Claim 1.

With regard to Claims 2-6, they are patentable at least for their dependency on allowable Claim 1.

Claims 22 – 26

With regard to Claim 22, Applicants reiterate the arguments of Claim 1 and have amended Claim 22 to reflect that the event logger determines *a number of fetal spatial presentation and/or position changes during a given period of time.* Since Nagel does not teach determining the fetal spatial presentation or positions or the number of spatial position changes to determine the health of the fetus, Applicants request reconsideration of Examiner's rejection of Claim 22.

With regard to Claims 23-26, they are patentable at least for their dependency on allowable Claim 22.

Claim Rejections – 35 USC §§ 103

Claims 7-11 and 27-30

These claims stand rejected over a combination of Nagel and Marossiero. With regard to Claim 7, Applicants have amended independent Claim 1 from which Claim 7 depends, to distinguish over Nagel.

In addition, Applicants argue that Marossiero is not prior art and cannot be cited against the current application. Marossiero was filed May 28, 2004 and published December 1, 2005. Applicants filed Patent Application GB 0324018.1 in the United Kingdom on October 14, 2003

and filed Patent Application GB 0324196.5 in the United Kingdom on October 16, 2003.

Applicant duly presented its claim for priority to these British patent applications upon the filing of the International Patent Application, and further upon entry of this Application into the U.S. national stage on 13 April 2006. Since the instant application properly claims priority back to these applications, Marossiero is not citable prior art under any section of 35 USC §102 and therefore cannot be used as a ground for obviousness under 35 USC §103.

Further, even if Marossiero were available as prior art, the Examiner's assertion that paragraph 183 of Marossiero teaches comparing ECG waveforms related to the movement of the fetus with a set of predetermined waveforms is erroneous.

While Marossiero uses many of the same terms as the current invention, Marossiero is directed to determining the position of the fetus. For example, Marossiero states in paragraph 183 that "As understood by a skilled clinician, different waveforms of fetal ECG signals have different shapes depending on the location/orientation of signal collection." Marossiero does not, however, disclose or suggest the detection of changes in fetal position or presentation, as all of Claims 1 – 21 require. Determining and documenting changes in the position of the fetus is substantially more complex than merely determining a static position of the fetus.

Further, there is no teaching, suggestion or motivation that Nagel and Marossiero can be combined, as Nagel continuously updates a single fetal ECG complex store. This average complex is computed by using a weighted average (referred to as "exponential averaging" – equation 4, Col. 14, line 31) of typically the last 16 fetal complexes; the averaging constant $U (=16)$ is referred to at Nagel, Col. 19, line 66. Nagel makes no attempt to discriminate one fetal complex from another based on a possible difference in fetal position, but simply averages them all.

Regarding Claim 8, this claim is at least patentable for its dependence on Claim 7. In addition, even were Marossiero available as prior art, Marossiero does not contemplate more than one electrode configuration. Paragraph 61 of that reference discloses precisely one such configuration and does not address the possibility of others.

Regarding Claim 9, this claim is at least patentable for its dependence on Claim 7. Additionally, Claim 9 is patentable because of its recitation of the event logger recording occasions on which the determined template changes. Examiner cites col. 3, lines 53-61 to support the contention that Nagel teaches changing of templates. Nagel does not teach changing of templates but instead teaches at that the system taking the readings filters out interfering signals. Conversely, Applicant's system matches the signal to a stored template. This allows the Applicants' system to determine the frequency of the fetus movements by counting the number of times the template has changed. Thus, the Applicants are not merely filtering noise out of the signal, but tracking the fetus's changes in presentation or position, which neither Nagel nor Marossiero attempt to do.

With regard to Claims 10 and 11, they are patentable at least for their dependency on allowable Claim 7.

Regarding Claim 27, Applicants reiterate their argument that Marossiero is not available as prior art. Further, neither reference discloses or suggests determining a number of changes in fetal presentation or position from ECG data. Further, as discussed in Claim 7, Nagel teaches average of all recent received ECG complexes and storing the result and it is impermissible to combine the two because Nagel teaches away from storing separate templates based on different fetal presentations.

Claim 28 is patentable at least for its dependency on Claims 27 and 22. Further, neither of these references discloses or suggests the determination of when the determined template changes. As discussed in Claim 9, Applicant's system matches the signal to a template, which allows the Applicants' system to determine the frequency of the fetus movements by counting the number of times the template has changed. Conversely, the Nagel merely teaches filtering noise out of the signal.

With regard to Claim 29, even supposing Marossiero to be available as prior art, Marossiero only teaches a single electrode configuration (Marossiero, Para. 61) and does not contemplate that there might be several such, or that a set of predetermined fetal ECG templates might be selected according to which one of these is used.

Claim 30 is patentable at least for its dependency on Claim 27.

Claims 12 – 14 and 32

These claims stand rejected over a combination of Nagel and Beach. Regarding Claim 12, the Examiner points in particular to Beach, column 4, lines 5 – 11, for the teaching of the use of a phase detector to determine the approximate phases for *ultrasounds* reflected at different depths. While Beach does teach the use of a means for detecting phase changes, it only does so generically and does not concern itself at all with maternal/fetal *ECG* complexes or the analysis of same, as these claims require. Further, since Beach does not teach determining the spatial orientation of the fetus and Nagel does not teach using a phase detector, there is no motivation to combine them. Moreover, neither Beach nor Nagel discloses or suggests how changes in fetal presentation or position can be detected from such phase changes.

Claims 13 and 32 are dependent at least for their dependency on Claims 12 and 22, respectively. Applicants reiterate their argument from Claim 12. Further, the Examiner's

reliance on column 11, lines 10-25 of Nagel is misplaced. In this section, Nagel discusses filtering of the received signal so that the fetal heartbeat can be distinguished from the mother's heartbeat and other background noise. Nagel is not referring to determining the phase change in the ultrasound wave to determine distance.

Claim 14 is patentable at least for its dependency on Claim 12.

Claims 15 – 21 and 34-39

These claims stand rejected over a combination of Nagel and Oriol. With regard to Claim 15, the Examiner points to Oriol's teaching, at column 9, lines 60 – 67 and Figure 5A thereof, which is a time plot of a baseline heart rate signal, and shows decelerations associated with loss of variability. This is very different from Claim 15 of the application.

Claims 15 and 34 are directed to detecting in a change in the relative proportion of energy of a fetal electrocardiogram complex within a segment of an ECG identified as a complex. The cited text and figure are directed to heart rate in beats per minute, decreases in heart rate, and the variability associated with the decelerations in heart rate. Additionally, Oriol does not teach a baseline, but superimposes a range of fetal heart rates on the graph in Fig. 5A.

Claims 16, 17, 35, and 36 are patentable at least for their dependence on Claims 15 and 22, respectively. Further, relative to Claims 16 and 35, Oriol does not teach using the isoelectric line as a baseline from which relative proportions of energy above and below this line can be derived. Additionally, the Examiner cites column 6, lines 5-14 to support the assertion that the reference is derived from a previous or average waveform. However, that section of Oriol only

generally discusses isolating the fetal heartbeat using computers, and does not discuss using a previous or average ECG complex waveform.

Claims 18, 20, 21, 37, and 39 are allowable at least from their dependency on Claim 1. Further, Applicants have amended the claims to more particularly point out that the “fetal changes” in question are selected from the group consisting of changes in fetal spatial presentation or position. Moreover, relative to Claims 20 and 39, the “warning” indication showing in the display of Figure 13 in Oriol is not related to whether a determined number of fetal positional changes during a period of time, which itself has been derived from fetal ECG complex data, falls below a predetermined threshold. Since Nagel does not teach determining the fetal spatial presentation or position or determining the number of spatial position changes to determine the health of the fetus, Applicants respectfully request reconsideration of the rejections to Claims 18, 20, and 21.

Claims 19 and 38 are allowable at least for their dependency on Claims 1 and 22, respectively.

Claims 31 and 33

These claims stand rejected based on a combination of Nagel and Beach. They are patentable for the reasons expressed relative to Claims 12 – 14.

Conclusion

The foregoing discussion shows how the claims as now amended patentably define over Nagel, either alone or in combination with any other references which is available to be cited as prior art to this Application.

This Reply to Examiner's Action is being submitted with a fee for a three month extension of time and a Request for Continued Examination (RCE). Applicant's amendments do not necessitate the payment of additional claim fees. Nonetheless, the Commissioner is hereby authorized to charge Deposit Account No. 503982 of Momkus McCluskey, LLC to cover any fee deficiency.

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